IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

THE RESEARCH FOUNDATION OF STATE UNIVERSITY OF NEW YORK; NEW YORK UNIVERSITY; GALDERMA LABORATORIES INC.; AND GALDERMA LABORATORIES, L.P., Plaintiffs, vs. MYLAN PHARMACEUTICALS INC. Defendant.	C.A. No. 09-184-LPS
MYLAN PHARMACEUTICALS INC., Plaintiff, vs. GALDERMA LABORATORIES INC.; GALDERMA LABORATORIES, L.P.; AND SUPERNUS PHARMACEUTICALS, INC. Defendants.	C.A. No. 10-892-LPS **REDACTED – PUBLIC VERSION**

DECLARATION OF PROFESSOR JERRY A. HAUSMAN IN SUPPORT OF GALDERMA'S RESPONSIVE BRIEF REGARDING REMEDY FOR INFRINGEMENT

MORRIS, NICHOLS, ARSHT & TUNNELL LLP
Jack B. Blumenfeld (# 1014)
Maryellen Noreika (# 3208)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899-1347
(302) 658-9200
jblumenfeld@mnat.com
mnoreika@mnat.com

Attorneys for The Research Foundation of State Univ. of New York; New York Univ.; Galderma Labs. Inc.; Galderma Labs., L.P.; and Supernus Pharm., Inc.

OF COUNSEL:

Gerald J. Flattmann, Jr.
Christine Willgoos
PAUL HASTINGS LLP
75 East 55th Street
New York, NY 10022
(212) 318-6000

Originally Filed: September 7, 2011
Redacted Version Filed: September 14, 2011

I, Jerry A. Hausman, declare as follows:

I. INTRODUCTION

1. I submitted a declaration in the matter of *Research Foundation of State University of New York et al. v. Mylan Pharmaceuticals, Inc.* (C.A. No. 09-184) on April 2, 2010, which I understand was submitted again in this matter on September 2, 2011 in support of Galderma's Opening Brief Regarding Remedy for Infringement (C.A. 09-184, D.I. 283). My background and qualifications are contained in that declaration. In this declaration I respond to the Declaration of Philip B. Nelson, Ph.D. ("Nelson Declaration") and the Declaration of Anthony Mauro ("Mauro Declaration"), both submitted by Mylan on September 2, 2011.

2. I have previously submitted a supplemental declaration in conjunction with Galderma's request for a preliminary injunction in this matter, and provided testimony at the preliminary injunction hearing. In connection with this declaration, I have reviewed the Court's August 26, 2011 Opinion and June 28, 2010 Preliminary Injunction Opinion, Mylan's and Galderma's opening briefing regarding post-trial remedies for Mylan's infringement, the Nelson and Mauro Declarations, my prior declarations in this matter, and other materials as described herein.

3. I understand that, according to the Court's August 26, 2011 Opinion, Mylan has been found to infringe each of 17 asserted claims of U.S. Patent No. 7,749,532 ("the Chang Patent"), all of which were found by the Court to be valid. I further understand that Mylan had previously stipulated that its generic version of Oracea® would infringe 15 of the 17 asserted claims of the Chang Patent. I also understand that, with respect to the Ashley Patents (U.S. Patent Nos. 7,211,267 and 7,232,572) that were the subject of the preliminary injunction, the Court held after trial that those patents were valid but not infringed.

II. SUMMARY OF OPINIONS

4. I have been asked by counsel for Galderma to consider two economic issues set forth in the Nelson and Mauro Declarations. First, I have been asked to evaluate Mylan's and Dr. Nelson's arguments regarding (1) whether Galderma will suffer irreparable harm for which monetary damages are inadequate if a permanent injunction is not granted; (2) the balance of hardships to Galderma and Mylan related to the granting of a permanent injunction; and (3) whether the public interest would be served by a permanent injunction. Second, I have been asked to consider [redacted]

5. As described more fully below, I have reached the following conclusions:

- In the absence of a permanent injunction, Galderma would suffer irreparable harm that could not be compensated by monetary damages. [redacted]
- The balance of hardships weighs in favor of granting a permanent injunction. Failing to grant a permanent injunction would irreparably harm Galderma, while Mylan will not suffer any irreparable harm if a permanent injunction is granted.
- By maintaining incentives for innovation in new drugs, granting a permanent injunction is in the public interest.

- [redacted]

III. ECONOMIC ANALYSIS OF ENTRY OF MYLAN'S GENERIC VERSION OF ORACEA®

6. Before describing my analysis of the permanent injunction, it is important to note that Mylan and Dr. Nelson confuse two unrelated economic issues in their analysis of a permanent injunction. The first issue is the amount of profits Mylan purportedly lost by being enjoined from making or selling generic Oracea® during the July 1-5, 2010 period. This issue involves a backward-looking analysis of the amount of product Mylan would have been able to sell during that period (taking into account returns from wholesalers), and the profits Mylan would have made on those sales, net of returns from wholesalers. The second issue relates to the harms and hardships that would be imposed on Galderma and Mylan depending on whether or not a permanent injunction is issued at the present time. This issue involves a forward-looking analysis of the effect of generic competition from Mylan with respect to Galderma's sales of Oracea®. These two issues are unrelated.[1]

[1] [redacted]

B. Irreparable Harm

7. [redacted]

8. As a result of its patent rights, Galderma is currently the sole source of 30 mg IR, 10 mg DR doxycycline capsules. [redacted]

[2] Apr. 2, 2010 Hausman Decl. ¶¶ 15-17, 20. I note that in the present situation, where Mylan seeks to expose Oracea® to an indefinite, ongoing period of generic competition, these harms will be even more severe and permanent than in the "interim" period of generic competition discussed in the context of the preliminary injunction.
[3] Nelson Decl. ¶ 18.
[4] Apr. 2, 2010 Hausman Decl. ¶ 22.
[5] Mauro Decl. ¶ 9.

9. [redacted]

C. Balance of Hardships

11. As I discuss above, in the absence of a permanent injunction, Galderma would be irreparably harmed. There is no irreparable harm to Mylan if the permanent injunction is

[6] Apr. 2, 2010 Hausman Decl. ¶ 17.
[7] Mauro Decl. ¶ 8.
[8] SUP 0054086-87 at SUP 0054086 (attached as Ex. 1).
[redacted]

granted, [redacted][10] Thus, the balance of hardships weighs in favor of granting the permanent injunction.

12. [redacted] A permanent injunction can have only future effects and cannot affect past events.

D. Public Interest

13. The patent system grants a patentee the right to exclude others from practicing the patent for a limited period of time. The right to exclude others is key to providing incentives for innovation, because it allows the patentee to maximize the return on its investment during the term of the patent. As I have previously explained, the exclusivity provided by patent rights is particularly important in protecting innovation incentives in the pharmaceutical industry because the total cost of bringing a new drug to market has been estimated to be approximately $800 million.[12] Thus, a permanent injunction is in the public interest because it preserves the incentives for innovation provided by the patent system, particularly for pharmaceuticals.

[10] Mauro Decl. ¶ 2.
[11] Nelson Decl. ¶ 19.
[12] May 14, 2010 Hausman Supplemental Decl. ¶ 34 (D.I. 140 (09-184)).

14. [redacted] Although the lower prices caused by generic entry, taken alone, would increase the benefit to consumers, the failure to grant a permanent injunction would reduce innovation incentives, thereby placing at risk the benefits consumers derive from new drugs in the future and causing harm to the public.

15. [redacted]

IV. [redacted]

16. [redacted]

[13] Nelson Decl. ¶ 29.
[14] Nelson Decl. ¶ 28.
[15] When a patent holder is a non-practicing entity ("NPE"), refusal to grant an injunction makes economic sense because consumers would not have the product available if an injunction issues. Indeed, NPEs typically use the threat of an injunction for negotiating leverage to demand a higher royalty rate because an NPE earns no profits if it does not license its patent. Here, in contrast, consumers are able to purchase Oracea® because Galderma can meet all consumer demand. While consumers would pay a lower price if a generic were available, the reduced profits would deter investment in future innovation. The tradeoff between higher profits and economic incentives to invest in innovation is the key tradeoff of the patent system, particularly in the context of pharmaceuticals. A compulsory license that leads to decreased prices contradicts the basic framework of the U.S. patent system and the Hatch-Waxman amendments.

[redacted]

[redacted]

[19] Given that Mylan admitted infringement of the Chang Patent, that the claims of the Chang Patent were found to be valid at trial, and that the Court has previously found that Galderma would be irreparably harmed by generic competition against Oracea®, Galderma would most likely have prevailed in obtaining a preliminary injunction with the Chang Patent.

18. I understand that, prior to July 1, 2010, Mylan knew of the pendency of the Chang Patent as a notice of allowance had been issued by the United States Patent and Trademark Office, and that Mylan later agreed that its generic product infringes 15 claims of the Chang Patent. [redacted]

19. [redacted]

Indeed, it is for these same reasons that at-risk launches of generic products are rare in general, occurring less than 10% of the time.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on September 7, 2011

Jerry A. Hausman, Ph.D.

CERTIFICATE OF SERVICE

I hereby certify that on September 7, 2011, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to:

Richard L. Horwitz, Esquire
David E. Moore, Esquire
POTTER ANDERSON & CORROON LLP

I further certify that I caused copies of the foregoing document to be served on September 7, 2011, upon the following in the manner indicated:

Richard L. Horwitz, Esquire — *VIA ELECTRONIC MAIL*
David E. Moore, Esquire
POTTER ANDERSON & CORROON LLP
Hercules Plaza – 6th Floor
1313 North Market Street
Wilmington, DE 19801

David S. Steuer, Esquire — *VIA ELECTRONIC MAIL*
Matthew J. Reed, Esquire
Michael D. Nguyen, Esquire
Kirin K. Gill, Esquire
WILSON SONSINI GOODRICH & ROSATI
650 Page Mill Road
Palo Alto, CA 94304

Tung-On (T.O.) Kong, Esquire — *VIA ELECTRONIC MAIL*
WILSON SONSINI GOODRICH & ROSATI
One Market Street
Spear Tower – Suite 3300
San Francisco, CA 94105

Lori P. Westin, Esquire — *VIA ELECTRONIC MAIL*
WILSON SONSINI GOODRICH & ROSATI
12235 El Camino Real
Suite 200
San Diego, CA 92130

/s/ Maryellen Noreika
Maryellen Noreika (#3208)

CERTIFICATE OF SERVICE

I hereby certify that on September 14, 2011, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to:

Richard L. Horwitz, Esquire
David E. Moore, Esquire
POTTER ANDERSON & CORROON LLP

I further certify that I caused copies of the foregoing document to be served on September 14, 2011, upon the following in the manner indicated:

Richard L. Horwitz, Esquire — *VIA ELECTRONIC MAIL*
David E. Moore, Esquire
POTTER ANDERSON & CORROON LLP
Hercules Plaza – 6th Floor
1313 North Market Street
Wilmington, DE 19801

David S. Steuer, Esquire — *VIA ELECTRONIC MAIL*
Matthew J. Reed, Esquire
Kirin K. Gill, Esquire
WILSON SONSINI GOODRICH & ROSATI
650 Page Mill Road
Palo Alto, CA 94304

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WILSON SONSINI GOODRICH & ROSATI
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Spear Tower – Suite 3300
San Francisco, CA 94105

Lori P. Westin, Esquire — *VIA ELECTRONIC MAIL*
WILSON SONSINI GOODRICH & ROSATI
12235 El Camino Real
Suite 200
San Diego, CA 92130

Maryellen Noreika (#3208)